

EPA Registration # 35935-99

NEW APPLICATIONS

DATE: OCT 11 2012

FILE NUMBER: 35935-00

FEP (OPPIN ENTRY) GM-LV OCT 12 2012
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

___ **ASSIGN TO PM** 20 **(NO DATA)**

___ **JACKET TO SHELF (DATA)**

E-SUBMISSION

Material Sent for Data Extraction

Reg. # 35935-99

Description: New manufacturing use product

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☒ Other: India R 310

☐ Decision #: 470782

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Banza Djanov

Phone: 305-7269 Division: RSB

Date: 5-20-13



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

EPA Reg.
35935-99

Date of
Issuance:
MAY 20 2013

Term of Issuance:
Unconditional

Name of Pesticide Product:
Myclobutanil Technical

Name and Address of Registrant (include ZIP Code):

Mr. Nathan P. Ehresman
Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

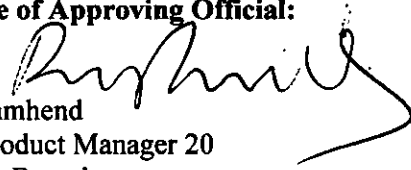
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

Signature of Approving Official:


Driss Benmhend
Acting Product Manager 20
Fungicide Branch
Registration Division (7504P)

Date:

MAY 20 2013

EPA Form 8570-6

2. Make the following change to the label:

a. Change the product registration number to "EPA Reg. No. 35935-99"

3. Submit one copy of the revised final printed label before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the label stamped "Accepted" is enclosed for your records.



Driss Benmhend
Acting Product Manager 20
Fungicide Branch
Registration Division (7504P)

Enclosures:

Label stamped "Accepted"
Product Chemistry Review DP
Acute Toxicity Review DP

MYCLOBUTANIL TECHNICAL

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Myclobutanil.....98.0%

OTHER INGREDIENTS:2.0%

TOTAL100.0%

EPA Reg. No. 35935-_____ EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

DANGER

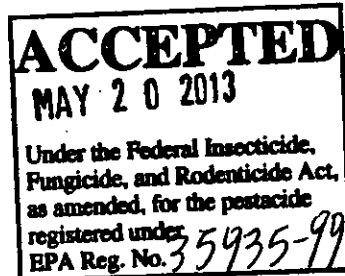
For Chemical Spill, Leak, Fire, or Exposure Call CHEMTREC (800) 424-9300

For Medical Emergencies Only Call (877) 325-1840

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • DO NOT induce vomiting unless told to do so by a poison control center or doctor. • DO NOT give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.	
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.	

NET WEIGHT: _____

Manufactured for:
NUFARM LIMITED
 4020 Aerial Center Parkway, Suite 101
 Morrisville, NC 27560



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. Causes irreversible eye damage. **DO NOT** get in eyes or on clothing. Harmful if inhaled, swallowed, or absorbed through skin. Wear goggles, safety glasses or face shield. Avoid contact with skin. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

DO NOT discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. **DO NOT** discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is intended for the formulation of fungicide products. This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s).

FOR MANUFACTURING USE ONLY INTO A FUNGICIDE FOR THE FOLLOWING USES:

1. Terrestrial Food Crops and Terrestrial Feed Crops:

Almonds, Apples, Apricots, Asparagus, Caneberries, Cherries, Cottonseed, Cucurbits, Currants, Gooseberries, Grapes, Hops, Mayhaws, Peppermint and Spearmint, Nectarines, Peaches, Plums, Prunes, Snap beans, Soybeans, Strawberries, Tomatoes.

2. Terrestrial Nonfood crop, Forestry, Residential Outdoor:

Hybrid poplar (nursery or forested areas used for wood pulp production), Douglas fir and Loblolly pine (nursery use only), turf and ornamental uses.

3. Uses for which the US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

4. Uses for experimental purposes that are in compliance with US EPA requirements

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Always use original container to store pesticides in a cool, dry secured warehouse or storage building. **DO NOT** store near food and feed. Containers should be opened in well-ventilated areas. Keep container tightly sealed when not in use.

PESTICIDE DISPOSAL: Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

Plastic or Paper Bags: Nonrefillable container. **DO NOT** reuse or refill this container. Completely empty bag into manufacturing equipment. Offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Rigid Plastic Containers: Nonrefillable container: **DO NOT** reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Fiber drums with liners: Nonrefillable container. **DO NOT** reuse or refill this container. Completely empty liner by shaking and tapping both sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then offer fiber drum and liner for recycling, if available.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

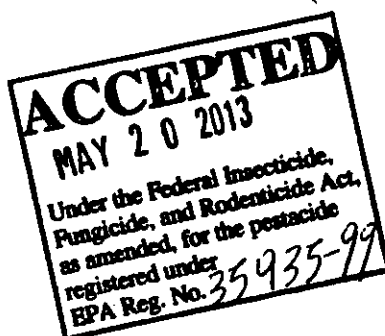
TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

RV051413

LABEL HISTORY

File Name	Revision Mark	Comment
035935-000XX.20120928.Draft_label	RV092812	Draft- Section 3
035935-000OO.20130514.Revised_Draft	RV051413	Revised Draft per EPA request



MYCLOBUTANIL TECHNICAL

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Myclobutanil.....98.0%

OTHER INGREDIENTS:.....2.0%

TOTAL.....100.0%

EPA Reg. No. 35935-_____ EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

DANGER

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✓ IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • DO NOT induce vomiting unless told to do so by a poison control center or doctor. • DO NOT give anything by mouth to an unconscious person.
* IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
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SUBMISSION

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HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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CORROSIVE. Causes irreversible eye damage. **DO NOT** get in eyes or on clothing. Harmful if inhaled, swallowed, or absorbed through skin. Wear goggles, safety glasses or face shield. Avoid contact with skin. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse. *Wearing gloves when handling plants.*

✓ Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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available

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

RV092812

LABEL HISTORY

File Name	Revision Mark	Comment
035935-000XX.20120928.Draft_label	RV092812	Draft- Section 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 35935-OO/Myclobutanil Technical
DP Barcode: 411687
PC Code: 128857

From: Marianne Lewis, Biologist
Insecticides/Rodenticides Branch
Registration Division (7505P)

To: Driss Benmhend, Acting PM 20
Fungicide Branch
Registration Division (7505P)

Applicant: Nufarm Americas, Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

[Handwritten signature] LIS
5/9/13

FORMULATION FROM EPA Reg. No. 35935-OO LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Myclobutanil:	98.0%
<u>Inert Ingredient(s):</u>	2.0%
Total	100.0%

- ACUTE TOX
COMPLETED

- NEW DATA
MATRIX
IN JACKET

- ML

BACKGROUND: The registrant is citing acute studies to support the registration of their new product, EPA Reg. No. 35935-OO. The MRID's are as follows: 141662 (81-1), 141663 (81-2), 403571-01 (81-3), 141663 (81-4), 141663 (81-5) and 403571-02 (81-6). The studies were conducted on the technical. Two (81-3 & 81-6) studies were reviewed and found to be acceptable by TSS/RD on 2/17/88.

After reviewing the studies and the CSF's for the subject product and the product tested in the studies, the EPA will allow the registrant to cite the studies listed above to support the registration of the subject product.

RECOMMENDATIONS:

- The acute toxicity studies cited are acceptable to support the registration of EPA Reg. No. 35935-OO

The acute toxicity profile for EPA Reg. No. 35935-OO is currently:

Acute Oral	III	Cited (LD ₅₀ = 1600 mg/kg)
Acute Dermal	IV	Cited (LD ₅₀ > 5000 mg/kg)
Acute Inhalation	IV	Cited (LC ₅₀ > 5.1 mg/L)
Primary Eye	I	Cited
Primary Dermal	IV	Cited
Skin sensitization	skin sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 035935-00

MYCLOBUTANIL TECHNICAL

SIGNAL WORD:

DANGER

PELIGRO

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, safety glasses), long sleeved shirt, long pants, shoes, and socks.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

(May pose an aspiration pneumonia hazard.)

Next page -

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Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category I. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Lewis, Marianne

From: nathan.ehresman@us.nufarm.com
Sent: Thursday, April 18, 2013 3:58 PM
To: Lewis, Marianne
Cc: nathan.ehresman@us.nufarm.com
Subject: Re: EPA Reg. No. 35935-OO - Myclobutanil Technical
Attachments: EPA-HQ-OPP-2006-0282-0006.pdf - Adobe Acrobat Pro.pdf;
035935-000OO.20130418.8570-35_(Matrix_Revised).pdf

Marianne-

I received your email. I also received your voicemail.

We wish to go forward with your option 2 below. We will cite specific MRIDs and also provide some additional supporting information in the form of US EPA review conclusions for myclobutanil.

Acute Oral Toxicity: MRID#s 00141662 (Rats) & 00141664 (Mice) TOX CATEGORY III
Acute Dermal Toxicity: MRID# 00141663 TOX CATEGORY IV
Acute Inhalation Toxicity: MRID# 40357101 TOX CATEGORY IV
Primary Skin & Eye Irritation: MRID# 00141663 TOX CATEGORY IV (SKIN) TOX CATEGORY I (EYE)
Dermal Sensitization: MRID# 40357102 TOX CATEGORY (Positive)

I attach with this email the most recent EPA review I was able to find that included a summary of the Acute Toxicity for Myclobutanil. I highlighted the HED tox summary on page 4 of the review. This review was issued in July 2006

2.1 Hazard Characterization: The toxicological database for myclobutanil is adequate support registration and tolerances. There are no data gaps. Myclobutanil has low acute toxicity with the exception for ocular irritation. It is toxicity category III for oral acute toxicity, category IV for dermal and inhalation acute toxicity and dermal irritation. Myclobutanil is category I for ocular irritation and the technical is a dermal sensitizer. However, formulation containing myclobutanil was not sensitizing. In rat subchronic and chronic toxicity studies, the prin

I also reference the product with US EPA registration number 42750-142 (98% Myclobutanil Technical) that was approved by US EPA on September 14, 2006. No acute toxicity data was submitted in support of the registration for this product. Therefore I am concluding that the registrant cited the data listed above as there is no other data available to cite. Given EPA made a determination on the precautionary statements for the 42750-142 registration which cited existing data, the Nufarm label which matches the 42750-142 label exactly for precautionary statements- I trust the above data will be sufficient.

I have attached a revised data matrix listing the studies Nufarm is citing (as detailed above). If anything further is required to complete the review, please don't hesitate to contact me.

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919.379.2515
Mobile: 919.930.4198
nathan.ehresman@us.nufarm.com

From: "Lewis, Marianne" <Lewis.Marianne@epa.gov>
To: "nathan.ehresman@us.nufarm.com" <nathan.ehresman@us.nufarm.com>,
Date: 04/17/2013 03:27 PM
Subject: EPA Reg. No. 35935-OO - Myclobutanil Technical

Nathan,

We have conducted a Similarity Screen for the 35935-OO product registration application. In the package you requested a "cite all" for the acute toxicity data. After reviewing similar products it was determined that there are numerous data gaps and deficiencies making data citation unfeasible. So there are a couple of options for you:

- 1) you can conduct new tox data for the subject product – if you choose to do this you will need to withdraw the package and resubmit when the data has been completed
- 2) You can cite specific MRID's for each acute tox requirement
- 3) You can opt to have Tox I for all requirements and positive for dermal sensitization – then you don't need to do the data just ask for a waiver and request Tox Category I and positive for dermal sens.

You have 10 business days to respond (by 5/1/13) or withdraw your application package.

If you have any questions please feel free to contact me.

Marianne Lewis,
Biologist
IRB/RD
703 308-8043

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE. If the reader of this message is not the intended recipient or an employee or agent responsible for delivering the message to this intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please delete, destroy, and do not save the message.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: 28 / MARCH / 2013

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: DP407308 EPA File Symbol No.: 35935-00
PRODUCT NAME: Myclobutanil Technical
COMPANY: Nufarm Limited.
FOOD USE [X] INTEGRATED FORMULATION [X]
PCC: 128857 Decision No. 470782
ACTION CODE: R310 Pesticidal use: Fungicide

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

[Handwritten signature] *SBM* *3/28/13*

TO: Banza Djapao, CRM / Shaja Joyner, RM 20
Fungicide Branch / RD (7505P)

INTRODUCTION:

The Registrant has submitted a basic CSF (dated: 09/28/2012) for a proposed TGA/MUP, and has also proposed a product specific label for registration of the aforesaid product under EPA File symbol 35935-00. The product chemistry data have been submitted under MRIDs: 489512-01, -02, -03 and -04.

[REDACTED] for Nufarm Limited, NC, USA.

Label text indicates that this proposed MUP is intended to be formulated into end-use products with food uses & other products with uses approved by EPA.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed MUP.

SUMMARY OF FINDINGS:

1. The proposed TGA/MUP contains the active ingredient: Myclobutanil (98.0%).
2. The overall mean of the active ingredient from the five batch analysis is 98.4% [MRID: 489512-02, Page 32].

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 407308 **EPA File Symbol No.:** 35935-OO **PRODUCT NAME:** Myclobutanil Technical

3. The proposed nominal concentration of the active ingredient in the MUP is 98.0%. The nominal concentration of the active ingredient matches with the label claim. This is in compliance with PR Notice 91-2. The certified limits of the proposed active ingredient and the associated impurities are described in MRID: 489512-01, page 37, & are attached with this review].

4. The CSF of the proposed TGA/MUP is filled out completely and correctly. This CSF has been reviewed by I.I.A. Branch on 10/19/2012 and they have concluded that it contains active ingredient and impurities only.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRID: 489512-01 & -02].

6. The quantification and identification of the active ingredient and its associated impurities were performed by LC-MS and NMR (MRID: 489512-02). The amount of water was determined by Karl Fischer volumetric titration. The method to determine the content of Fomesafen was validated with respect to selectivity, system precision, and linearity of response, range of linearity, assay accuracy and method precision.

Similar analytical techniques can also be applied for Enforcement Analytical Method.

7. Product chemistry Group A and Group B data requirements are satisfied [MRIDs: 489512-01, -02, -03 and -04].

8. The registrant stated that no nitrosamines are expected to be formed since there was no nitration step was involved in the synthesis. Additionally, the registrant stated that Polychlorinated biphenyls, dibenzodioxins and dibenzofurans are not expected to be present in the formulation [MRID: 489512-01, page 35].

CONCLUSIONS:

1. TRB has reviewed the CSF (dated: 09/28/2012) for the proposed TGA/MUP and has found it to be acceptable.

2. Product chemistry Group A and Group B data requirements are satisfied and acceptable [MRIDs: 489512-01, -02, -03 and -04].

3. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

DP BARCODE No.: 407308 **EPA File Symbol No.:** 35935-OO **PRODUCT NAME:** Myclobutanil Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 11/23/2009)	A	489512-01 & - 02
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis	A	489512-02
830.1750. Certified Limits	A	489512-01
830.1800. Enforcement Analytical Method	A	489512-02

A = Acceptable NA = Not Applicable

DP BARCODE No.: 407308 EPA File Symbol No.: 35935-OO PRODUCT NAME: Myclobutanil Technical

Group – B	<u>Data Require d Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
830.6302. Color	A	Off White	489512-03
830.6303. Physical State	A	Powder	"
830.6304. Odor	A	Mild	"
830.6313. Stability to normal and elevated temp, metals and metal ions	A	Stable when exposed to normal & elevated temp and metals & metal ions	"
830-6314. Oxidation/Reduction action – Chemical incompatibility	A	No significant temp changes.	"
830.6315. Flammability	A	It is a solid NA	"
830.6316. Explodability	A	Not explosive.	"
830.6317. Storage stability	A	Stable	489512-04
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	A	Not corrosive	489512-04
830.7200. Melting point	A	63-68 °C	489512-03-Cited
830.7220. Boiling point	A	202-208° C	" Cited
830.7050. UV/visible light absorption	A	Neutral Media: Max at 221 nm was 1.044 AU. Acid Media: Max at 220 nm was 1.462 AU. Basic Media at 221.4 nm was 1.018 AU	"
830.7100 Viscosity	A	Solid / NA	"
830.7370. Dissociation Constant	A	Does not dissolve in water	"
830.7550. Partition Coefficient	A	Log Kow = 2.94	" Cited

830.7950. Vapor Pressure	A	0.0213 mPa @ 25°C	" Cited
830.7840. Solubility	A	In water = 142 mg/L @ 25°C ; In Methanol 768 g/L, In n-Octanol 153 g/L, In Hexane 1.70 g/L	"
830.7000. pH	A	6.0	"
830.7300. Density	A	0.5276 g/cm ³	"

Explanations: A = Acceptable, NA = Not applicable, G = Data gap

DATA PACKAGE BEAN SHEET

Date: 05-Dec-2012

Page 1 of 2

Decision #: 470782

DP #: (407308)

PRIA

Parent DP #:

Submission #: 925407

E-Sub #: 3503

*** Registration Information ***

Registration: 35935-OO - MYCLOBUTANIL TECHNICAL

Company: 35935 - NUFARM LIMITED

Risk Manager: RM 20 - Shaja Joyner - (703) 308-3194 Room# PY1

Risk Manager Reviewer: Banza Djapao BDJAPAO

Sent Date:

PRIA Due Date: 03-Jun-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE

Ingredients: 128857, Myclobutanil(98%)

R310
#3512

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Dec-2012

Due Back:

DP Ingredient: 128857, Myclobutanil

DP Title: Product chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 04-May-2013

Team Name: CHEM

Science Due Date:

Reviewer Name:

HARI MUKHOTY

03/27/13

03/28/13

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the data in documentum with MRIDs 48951200, 48951201, 48951202, 48951203, 48951204.
Is the prod chem acceptable? Are any changes required to the label?

Questions? Banza Djapao 305-7269

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48951200		Nufarm Limited (2012) Submission of Product Chemistry Data in Support of the Application for Registration of Myclobutanil Technical. Transmittal of 4 Studies.		
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1550/Product Identity and composition	Pass (19-Oct-2012)
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1600/Description of materials used to produce the product	Pass (19-Oct-2012)
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1650/Description of formulation process	Pass (19-Oct-2012)
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1670/Discussion of formation of impurities	Pass (19-Oct-2012)
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1750/Certified limits	Pass (19-Oct-2012)
48951201		Cooke, A. (2012) Technical Myclobutanil, NUP-07116: Product Identity and Process. Project Number: RTP/12/060/REG/OCR. Unpublished study prepared by Nufarm Americas, Inc. 121p.	830.1800/Enforcement analytical method	Pass (19-Oct-2012)
48951202		Hongxia, L. (2009) Preliminary Analysis and Enforcement Analytical Method of Myclobutanil TGA1 - Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Myclobutanil TGA1: Final Report. Project Number: NC/2009/032/OCR. Unpublished study prepared by Nutrichem Laboratory Co., Ltd. 132p.	830.1800/Enforcement analytical method	Pass (19-Oct-2012)
48951203		Leapard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.6302/Color	Pass (19-Oct-2012)
48951203		Leapard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.6303/Physical state	Pass (19-Oct-2012)

DP#: (407308)

*** Studies Sent for Review ***

Decision#: (470782)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.6304/Odor	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.6314/Oxidizing or reducing action	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7000/pH	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7100/Viscosity	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7200/Melting point/melting range	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7220/Boiling point/boiling range	Pass (19-Oct-2012)

DP#: (407308)

*** Studies Sent for Review ***

Decision#: (470782)

MRID	MRID Status	Citation Reference	Guideline	86.5 Status
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7300/Density/relative density	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7560/Partition coefficient (n-octanol/water), generator column method	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7570/Partition coefficient (n-octanol/water), estimation by liquid chromatography	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7840/Water solubility: Column elution method, shake flask method	Pass (19-Oct-2012)
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7860/Water solubility, generator column method	Pass (19-Oct-2012)

DP#: (407308)

*** Studies Sent for Review ***

Decision#: (470782)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48951203		Leopard, J. (2008) Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation/Reduction: Chemical Incompatibility; pH; UV/Visible Absorption; Melting Point/Melting Range; Boiling Point/Boiling Range; Density; Partition coefficient (n-Octanol/Water); Solubility; Vapor Pressure: Myclobutanil Technical. Project Number: CHB/EX/509/018/P/1/OCR. Unpublished study prepared by PhibroWood, LLC. 48p.	830.7950/Vapor pressure	Pass (19-Oct-2012)
48951204		Miller, R. (2008) Storage Stability and Corrosion Characteristics of Myclobutanil Technical: Final Report. Project Number: CHB/EX/510/OCR. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 39p.	830.6317/Storage stability	Pass (19-Oct-2012)
48951204		Miller, R. (2008) Storage Stability and Corrosion Characteristics of Myclobutanil Technical: Final Report. Project Number: CHB/EX/510/OCR. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 39p.	830.6320/Corrosion characteristics	Pass (19-Oct-2012)



NUFARM AMERICAS INC.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919-379-2515

September 28, 2012

Attn: Shaja Joyner / PM 20
Document Processing Desk (E-SUB)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Nufarm Ltd (Company # 55146) c/o Nufarm Americas Inc.**
MYCLOBUTANIL TECHNICAL (EPA Reg. No. 35935-____ (not yet assigned)
Application For Registration- PRIA R310

Dear Ms. Joyner:

Nufarm Ltd is submitting the enclosed application for registration of Myclubutanil Technical. The Nufarm Myclubutanil Technical is identical or substantially similar in composition & labeling to RH-3866 Technical (62719-407) and Myclubutanil TGA1 (42750-142). We are submitting this application for registration using the CITE-ALL option under the selective method of data support to address generic myclubutanil data requirements. We have enclosed 3 study volumes to address the product specific OPPTS series 830 product chemistry guidelines.

Nufarm has determined that this action falls under PRIA Category R310. We have pre-paid the service fee for this action and provide the following records of payment:

Pay.gov Tracking ID: 2584C2H8
Agency Tracking ID: 74361211434

In support of this action, please find enclosed 1 CD Containing:

- Application for Pesticide Registration (8570-1)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix- Agency Internal & Public Use Copies (8570-35)
- Confidential Statement of Formula (8570-4)
- Proposed Label-
- Certification with Respect to Label Integrity for electronic copy of label.
- Study Volumes 2, 3 and 4 (Product Chemistry)

Please contact me at 919-379-2515 (or nathan.ehresman@us.nufarm.com) if you have any questions regarding this action.

Kind regards,

A handwritten signature in black ink, appearing to read "N. Ehresman", with a long horizontal line extending to the right.

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.

Subdivision D: Product Chemistry

Vol. No.	OPPTS No.	EPA GLN	Study References	MRID No.
1	N/A	N/A	Administrative Documents	48951200
2	830.1550 830.1600 830.1650 830.1670 830.1750 830.1800	61-1 61-2 61-2 61-3 62-2 62-3	Cooke, A. Myclobutanil Technical, NUP-07116 Product Identity and Process. August 6, 2012. Study Number RTP-12-060-REGC. 121 pages.	48951201
3	830.1700 830.1800	62-1 62-3	Li, H. Preliminary Analysis and Enforcement Analytical Method of Myclobutanil TGAI- Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Myclobutanil TGAI. October 13, 2009. Study Number NC-2009-032. 132 pages.	48951202
4	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6321 830.7000 830.7050 830.7100 830.7200 830.7220 830.7300 830.7370 830.7570 830.7840 830.7950	63-2 63-3 63-4 63-13 63-14 63-15 63-16 63-21 63-12 N/A 63-18 63-5 63-6 63-7 63-10 63-11 63-8 63-9	Leopard, J. Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation / Reduction: Chemical Incompatibility; pH; UV / Visible Absorption; MeltingPoint / Melting Range; Boiling Point/Boiling Range; Density; Partition Coefficient (n-octanol / water); Solubility; Vapor Pressure. August 1, 2008. Study Number CHB-EX-509-018-P-1. 48 pages.	48951203
5	830.6317 830.6320	63-17 63-20	Miller, R. Final Report for Storage Stability and Corrosion Characteristics of Myclobutanil Technical. June 30, 2008. Study Number CHB-Ex-510. 39 pages.	48951204

DP BARCODE No.: 407308 **EPA File Symbol No.:** 35935-OO **PRODUCT NAME:** Myclobutanil Technical

CONFIDENTIAL APPENDIX

Pages 34-61 *Manufacturing process information may be entitled to confidential treatment*

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MYCLOBUTANIL TECHNICAL

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Myclobutanil.....98.0%

OTHER INGREDIENTS:2.0%

TOTAL100.0%

EPA Reg. No. 35935-_____ EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN DANGER

For Chemical Spill, Leak, Fire, or Exposure Call CHEMTREC (800) 424-9300
For Medical Emergencies Only Call (877) 325-1840

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• DO NOT induce vomiting unless told to do so by a poison control center or doctor.• DO NOT give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.	

NET WEIGHT: _____

Manufactured for:
NUFARM LIMITED
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560



SUBMISSION

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

CORROSIVE. Causes irreversible eye damage. **DO NOT** get in eyes or on clothing. Harmful if inhaled, swallowed, or absorbed through skin. Wear goggles, safety glasses or face shield. Avoid contact with skin. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

DO NOT discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. **DO NOT** discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is intended for the formulation of fungicide products. This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s).

FOR MANUFACTURING USE ONLY INTO A FUNGICIDE FOR THE FOLLOWING USES:

1. Terrestrial Food Crops and Terrestrial Feed Crops:

Almonds, Apples, Apricots, Asparagus, Caneberries, Cherries, Cottonseed, Cucurbits, Currants, Gooseberries, Grapes, Hops, Mayhaws, Peppermint and Spearmint, Nectarines, Peaches, Plums, Prunes, Snap beans, Soybeans, Strawberries, Tomatoes.

2. Terrestrial Nonfood crop, Forestry, Residential Outdoor:

Hybrid poplar (nursery or forested areas used for wood pulp production), Douglas fir and Loblolly pine (nursery use only), turf and ornamental uses.

3. Uses for which the US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

4. Uses for experimental purposes that are in compliance with US EPA requirements

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Always use original container to store pesticides in a cool, dry secured warehouse or storage building. **DO NOT** store near food and feed. Containers should be opened in well-ventilated areas. Keep container tightly sealed when not in use.

PESTICIDE DISPOSAL: Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

Plastic or Paper Bags: Nonrefillable container. **DO NOT** reuse or refill this container. Completely empty bag into manufacturing equipment. Offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Rigid Plastic Containers: Nonrefillable container. **DO NOT** reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Fiber drums with liners: Nonrefillable container. **DO NOT** reuse or refill this container. Completely empty liner by shaking and tapping both sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then offer fiber drum and liner for recycling, if available.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF, THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

RV092812

LABEL HISTORY

File Name	Revision Mark	Comment
035935-000XX.20120928.Draft_label	RV092812	Draft- Section 3

Fungicide Branch Assignment Sheet

Date Delivered to PM

10/26/12
(date & initial)

Mary Waller
PM 21

Tony Kish
PM 22

Acting PM 20

Risk Managers

Tamue

Erin

Heather

Rose

Dominic

Summer

Shaunta

Bob

Banza

Comments to Summer

Comments to Risk Manager

Date to Summer

10/31/12 MC
(date & initial)

Date to Risk Manager

(date stamp & initial area below)

To the Document Center (ITRMD)

*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section: **PM -5**

Insecticide Branch: **PM -10** **PM-13**

Herbicide Branch: **PM-23** **PM-25**

Fungicide Branch: **PM-20** **PM-21** **PM-22**

Insect/Rodent Branch: **PM-1** **PM-7**

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team

Steve Achaile
(Team Member Signature)

10/24/12
(Date)



NUFARM AMERICAS INC.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919-379-2515

September 28, 2012

Attn: Shaja Joyner / PM 20
Document Processing Desk (E-SUB)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Nufarm Ltd (Company # 55146) c/o Nufarm Americas Inc.**
MYCLOBUTANIL TECHNICAL (EPA Reg. No. 35935-____ (not yet assigned)
Application For Registration- PRIA R310

Dear Ms. Joyner:

Nufarm Ltd is submitting the enclosed application for registration of Myclubutanil Technical. The Nufarm Myclobutanil Technical is identical or substantially similar in composition & labeling to RH-3866 Technical (62719-407) and Myclobutanil TGA1 (42750-142). We are submitting this application for registration using the CITE-ALL option under the selective method of data support to address generic myclobutanil data requirements. We have enclosed 3 study volumes to address the product specific OPPTS series 830 product chemistry guidelines.

Nufarm has determined that this action falls under PRIA Category R310. We have pre-paid the service fee for this action and provide the following records of payment:

Pay.gov Tracking ID: 2584C2H8
Agency Tracking ID: 74361211434

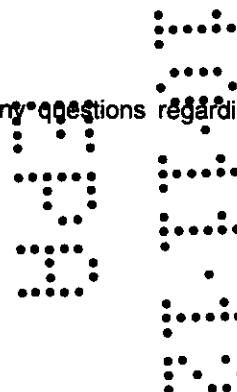
In support of this action, please find enclosed 1 CD Containing:

- Application for Pesticide Registration (8570-1)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix- Agency Internal & Public Use Copies (8570-35)
- Confidential Statement of Formula (8570-4)
- Proposed Label-
- Certification with Respect to Label Integrity for electronic copy of label.
- Study Volumes 2, 3 and 4 (Product Chemistry)


Please contact me at 919-379-2515 (or nathan.ehresman@us.nufarm.com) if you have any questions regarding this action.

Kind regards,

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.



E-SUBMISSION

 EPA United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Nufarm Ltd 35935-__ (not yet assigned)	2. EPA Product Manager Shaja Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nufarm Limited/ MYCLOBUTANIL TECHNICAL	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No.: <u>62719-407</u> / <u>42750-142</u> Product Name: <u>RH-3866 Technical</u> / <u>Myclobutanil TGA</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**Application for Registration****PRIA CATEGORY: R310** ; New manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: product chemistry

Pay.gov Tracking ID: 2584C2H8

Agency Tracking ID: 74361211434

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 25, 50, 100 kg	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Nathan P. Ehresman	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 919-379-2515
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Nathan P. Ehresman	4. Date September 28, 2012	

Subdivision D: Product Chemistry

Vol. No.	OPPTS No.	EPA GLN	Study References	MRID No.
1	N/A	N/A	Administrative Documents	48951200
2	830.1550 830.1600 830.1650 830.1670 830.1750 830.1800	61-1 61-2 61-2 61-3 62-2 62-3	Cooke, A. Myclobutanil Technical, NUP-07116 Product Identity and Process. August 6, 2012. Study Number RTP-12-060-REGC. 121 pages.	48951201
3	830.1700 830.1800	62-1 62-3	Li, H. Preliminary Analysis and Enforcement Analytical Method of Myclobutanil TGAI- Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Myclobutanil TGAI. October 13, 2009. Study Number NC-2009-032. 132 pages.	48951202
4	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6321 830.7000 830.7050 830.7100 830.7200 830.7220 830.7300 830.7370 830.7570 830.7840 830.7950	63-2 63-3 63-4 63-13 63-14 63-15 63-16 63-21 63-12 N/A 63-18 63-5 63-6 63-7 63-10 63-11 63-8 63-9	Leapard, J. Product Properties: Color; Physical State; Odor; Stability to Normal and Elevated Temperatures, Metals and Metal Ions; Oxidation / Reduction: Chemical Incompatibility; pH; UV / Visible Absorption; MeltingPoint / Melting Range; Boiling Point/Boiling Range; Density; Partition Coefficient (n-octanol / water); Solubility; Vapor Pressure. August 1, 2008. Study Number CHB-EX-509-018-P-1. 48 pages.	48951203
5	830.6317 830.6320	63-17 63-20	Miller, R. Final Report for Storage Stability and Corrosion Characteristics of Myclobutanil Technical. June 30, 2008. Study Number CHB-Ex-510. 39 pages.	48951204

E-SUBMISSION

Djapao, Banza

From: nathan.ehresman@us.nufarm.com
Sent: Tuesday, May 14, 2013 3:29 PM
To: Djapao, Banza
Cc: Benmhend, Driss
Subject: Re: Revised label for Myclobutanil Technical -reg#35935-OO
Attachments: 035935-000OO.20130514.Revised_Draft.pdf

Banza,

I have attached a revised label. I added the note to physician and made the correction on the recycling statement- if available.

If further is needed on the Note To Physician, could you let me know. I checked the label review manual and PRN 2001-1 and we seem to have addressed the Agency requirement with the revision I made. We have a number of products with the Danger classification category I and have always used the statement regarding "gastric lavage" being contraindicated.

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919.379.2515
Mobile: 919.930.4198
nathan.ehresman@us.nufarm.com

From: "Djapao, Banza" <Djapao.Banza@epa.gov>
To: "nathan.ehresman@us.nufarm.com" <nathan.ehresman@us.nufarm.com>,
Cc: "Benmhend, Driss" <Benmhend.Driss@epa.gov>
Date: 05/14/2013 01:44 PM
Subject: Revised label for Myclobutanil Technical -reg#35935-OO



Hi Mr Nathan

You have to add the following information for the product name Myclobutnail Technical -reg# 35935-OO:
Note to physician : Probable mucosal may contraindicate the use of gastric lavage.

The proposed label should contain a note to physician which addresses the primary eye irritation toxicity category I. The following statements are some suggested types of information that could be included , if applicable, in the note to physicians:

Technical information on symptomatology, use of supportive treatments to maintain life functions, medicine

that will counteract the specific physiological effects of the pesticide, company telephone number to specific medial personnel who can provide specialized medical advice.

Additionally, you have to add a missing statement in the storage and disposal section : "...then offer for recycling "if available" (see rigid plastic containers)

Yours,

Banza Djapao
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7504P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(W): (703)305-7269
(Fax): (703)305-6920
<http://www.epa.gov/pesticides>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE. If the reader of this message is not the intended recipient or an employee or agent responsible for delivering the message to this intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please delete, destroy, and do not save the message.

Nufarm Americas Inc. and its affiliated companies.
Fax: +1 630 455 2001.

"mold label"

MYCLOBUTANIL TECHNICAL

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Myclobutanil.....98.0%

OTHER INGREDIENTS:2.0%

TOTAL100.0%

EPA Reg. No. 35935-_____ EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure Call CHEMTREC (800) 424-9300
For Medical Emergencies Only Call (877) 325-1840

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• DO NOT induce vomiting unless told to do so by a poison control center or doctor.• DO NOT give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.	

NET WEIGHT: _____

Manufactured for:
NUFARM LIMITED
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

CORROSIVE. Causes irreversible eye damage. **DO NOT** get in eyes or on clothing. Harmful if inhaled, swallowed, or absorbed through skin. Wear goggles, safety glasses or face shield. Avoid contact with skin. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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1. Terrestrial Food Crops and Terrestrial Feed Crops:

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4. Uses for experimental purposes that are in compliance with US EPA requirements

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Fiber drums with liners: Nonrefillable container. **DO NOT** reuse or refill this container. Completely empty liner by shaking and tapping both sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then offer fiber drum and liner for recycling, if available.

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

RV051413

LABEL HISTORY

File Name	Revision Mark	Comment
035935-000XX.20120928.Draft_label	RV092812	Draft- Section 3
035935-000OO.20130514.Revised_Draft	RV051413	Revised Draft per EPA request



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	EPA Registration Number/ File Symbol 35935-__
Active Ingredient(s) and/or representative test compound(s): Myclobutanil (PC code 128857)	Date September 28, 2012
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food; Terrestrial feed; Terrestrial nonfood; Forestry; Residential outdoor	Product Name Myclobutanil Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date September 28, 2012	Typed or Printed Name and Title Nathan P. Ehresman / Director, Regulatory Affairs
---------------	-----------------------------------	---

Fee for Service

{925407*~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 20

Receipt No.

S-

925407

EPA File Symbol/Reg. No.

35935-OO

Pin-Punch Date:

10/11/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R-31D

Granted: R-31D

Amount Due: \$ 4807.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Venus Eagle

Date: 10/17/12

Remarks:

New Technical claiming similarity to 62719-407 with cited tox data.

ESUBMISSION



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 28, 2012

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 830	GROUP A- PRODUCT IDENTITY, COMPOSITION & ANALYSIS				
830.1550	Product identity and composition	48951201	Nufarm Limited (035935)	Own	
830.1600	Description of materials used to produce the product	48951201	Nufarm Limited (035935)	Own	
830.1620	Description of production process	48951201	Nufarm Limited (035935)	Own	
830.1650	Description of formulation process	--	--	N/A	1
830.1670	Discussion of formation of impurities	48951201	Nufarm Limited (035935)	Own	
830.1700	Preliminary analysis	48951202	Nufarm Limited (035935)	Own	
830.1750	Certified limits	48951201	Nufarm Limited (035935)	Own	
830.1800	Enforcement analytical method	48951201	Nufarm Limited (035935)	Own	
830.1900	Submittal of samples	--	--	N/A	2
	GROUP B- PHYSICAL/CHEMICAL PROPERTIES				
830.6302	Color	48951203	Nufarm Limited (035935)	Own	
830.6303	Physical state	48951203	Nufarm Limited (035935)	Own	
830.6304	Odor	48951203	Nufarm Limited (035935)	Own	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	48951203	Nufarm Limited (035935)	Own	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

September 28, 2012



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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

830.6314	Oxidation/reduction: chemical incompatibility	48951203	Nufarm Limited (035935)	Own	
830.6315	Flammability	48951203	Nufarm Limited (035935)	Own	
830.6316	Explosibility	48951203	Nufarm Limited (035935)	Own	
830.6317	Storage stability	48951204	Nufarm Limited (035935)	Own	
830.6319	Miscibility	48951203	Nufarm Limited (035935)	Own	
830.6320	Corrosion characteristics	48951204	Nufarm Limited (035935)	Own	
830.6321	Dielectric breakdown voltage	48951203	Nufarm Limited (035935)	Own	
830.7000	pH	48951203	Nufarm Limited (035935)	Own	
830.7050	UV/Visible absorption	48951203	Nufarm Limited (035935)	Own	
830.7100	Viscosity	48951203	Nufarm Limited (035935)	Own	
830.7200	Melting point/melting range	48951203	Nufarm Limited (035935)	Own	
830.7220	Boiling point/boiling range	48951203	Nufarm Limited (035935)	Own	
830.7300	Density/relative density/bulk density	48951203	Nufarm Limited (035935)	Own	
830.7370	Dissociation constants in water	48951203	Nufarm Limited (035935)	Own	
830.7520	Particle size, fiber length, and diameter distribution	—	—	N/A	3
830.7550	Partition coefficient (n-octanol/water), shake flask method	48951203	Nufarm Limited (035935)	Own	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

830.7840	Water solubility: column elution method; shake flask method	48951203	Nufarm Limited (035935)	Own	
830.7950	Vapor pressure	48951203	Nufarm Limited (035935)	Own	

Footnotes:

- 1 OPPTS 830.1650 Description of Formulation Process data are not required since Myclobutanil Technical is a technical grade active ingredient and is produced by an integrated process. 40 CFR § 158.310 (e) (3)
- 2 OPPTS 830.1900 Submittal of samples data is not required since a sample of Myclobutanil (PAI) has been provided by the Basic manufacturer. 40 CFR § 158.310 (e) (9.11)
- 3 OPPTS 830.7520 Particle size, Fiber Length, and Diameter Distribution data is not required as Myclobutanil Technical is not water insoluble or fibrous. 40 CFR § 158.310 (e) (14)

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 835	FATE, TRANSPORT AND TRANSFORMATION				
835.1110 – 835.1410	GROUP A- LABORATORY TRANSPORT	CITE-ALL	–	PAY	
835.2120 – 835.2410	GROUP B- LABORATORY ABIOTIC TRANSFORMATION	CITE-ALL	–	PAY	
835.3100 – 835.3420	GROUP C- LABORATORY BIOLOGICAL TRANSFORMATION	CITE-ALL	–	PAY	
835.4100 – 835.4300	GROUP D- TRANSFORMATION IN WATER AND SOIL	CITE-ALL	–	PAY	
835.5045 – 835.4400	GROUP E- TRANSFORMATION CHEMICAL SPECIFIC	CITE-ALL	–	PAY	
835.6100 – 835.6400	GROUP F- FIELD DISSIPATION	CITE-ALL	–	PAY	
835.7100	GROUP G- GROUND WATER MONITORING	CITE-ALL	–	PAY	
835.8100	GROUP H- VOLATILITY FROM SOIL	CITE-ALL	–	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 840	SPRAY DRIFT				
840.1000 – 840.1200	SPRAY DRIFT	CITE-ALL	-	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 850	ECOLOGICAL EFFECTS				
850.1010 – 850.1950	GROUP A- AQUATIC FAUNA	CITE-ALL	–	PAY	
850.2100 – 850.2500	GROUP B- TERRESTRIAL WILDLIFE	CITE-ALL	–	PAY	
850.3020 – 850.3040	GROUP C- BENEFICIAL INSECTS & INVERTEBRATES	CITE-ALL	–	PAY	
850.4000 – 850.4800	GROUP D- NONTARGET PLANTS	CITE-ALL	–	PAY	
850.5100 – 850.5400	GROUP E- TOXICITY TO MICROORGANISMS	CITE-ALL	–	PAY	
850.6200 – 850.6800	GROUP F- CHEMICAL SPECIFIC	CITE-ALL	–	PAY	

Signature

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 860					
860.1000 – 860.1900	RESIDUE CHEMISTRY	CITE-ALL	—	PAY	

Signature

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 870	HEALTH EFFECTS				
870.1100 – 830.2600	GROUP A- ACUTE TOXICITY	CITE-ALL	--	PAY	
870.3050 – 870.3800	GROUP B- SUBCHRONIC TOXICITY	CITE-ALL	--	PAY	
870.4100 – 870.4300	GROUP C- CHRONIC TOXICITY	CITE-ALL	--	PAY	
870.5100 – 870.5915	GROUP D- GENETIC TOXICITY	CITE-ALL	--	PAY	
870.6100 – 870.6855	GROUP E- NEUROTOXICITY	CITE-ALL	--	PAY	
870.7200 – 870.7800	GROUP F- SPECIAL STUDIES	CITE-ALL	--	PAY	
870.8223 – 870.8800	GROUP G- CHEMICAL SPECIFIC	CITE-ALL	--	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 875	OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.1100 – 875.1600	GROUP A- APPLICATOR EXPOSURE MONITORING	CITE-ALL	–	PAY	
875.2100 – 875.2900	GROUP B- POSTAPPLICATION EXPOSURE MONITORING	CITE-ALL	–	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

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Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 890	ENDOCRINE DISRUPTOR SCREENING				
890.1100 – 890.1600	EDSP TIER 1	CITE-ALL	–	PAY	

Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date September 28, 2012
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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
LIST OF COMPANIES SENT OFFER TO PAY FOR USE OF CITE-ALL METHOD OF DATA SUPPORT					
		CITE-ALL	SYNGENTA CROP PROTECTION, INC. / 000100	PAY	
		CITE-ALL	BAYER CROPSOURCE LP / 000264	PAY	
		CITE-ALL	VOLUNTARY PURCHASING GROUPS, INC / 007401	PAY	
		CITE-ALL	CHEMSICO / 009688	PAY	
		CITE-ALL	AGAN CHEM MFG, LTD	PAY	
		CITE-ALL	ALBAUGH INC / 042750	PAY	
		CITE-ALL	DOW AGROSCIENCES LLC / 062719	PAY	
		CITE-ALL	ARYSTA LIFESOURCE NORTH AMERICA, LLC	PAY	
		CITE-ALL	SPRAY DRIFT TASK FORCE / 066607	OWN	1
		CITE-ALL	OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, L.L.C. / 071754	OWN	1
		CITE-ALL	AGRICULTURAL REENTRY TASK FORCE / 071755	OWN	1
		CITE-ALL	FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C. / 073989	OWN	1
		CITE-ALL	RESIDENTIAL EXPOSURE JOINT VENTURE (REJV) / 074888	OWN	1
		CITE-ALL	AGRICULTURAL HANDLERS EXPOSURE TASK FORCE / 075234	OWN	1
		CITE-ALL	US TRIAZOLE TASK FORCE / 075576	PAY	

FOOTNOTES:

1 Nufarm Limited is a member of this task force.

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

September 28, 2012



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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			-	N/A	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			-	N/A	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	
			Nufarm Limited (035935)	Own	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
Nufarm Limited (035935)	Own
--	N/A
Nufarm Limited (035935)	Own

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

September 28, 2012



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Date: September 28, 2012

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Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Nufarm Limited (035935)

Own

Nufarm Limited (035935)

Own

Footnotes

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

September 28, 2012



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C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			--	PAY	
			--	PAY	
			--	PAY	
			--	PAY	
			--	PAY	
			--	PAY	
			--	PAY	
			--	PAY	

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Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date September 28, 2012
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			-	PAY	
			-	PAY	
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Ingredient: Myclobutanil (PC Code 128857)

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			—	PAY	
			—	PAY	
			—	PAY	
			—	PAY	
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C/O Nufarm Americas Inc.
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Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

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Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

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Ingredient: Myclobutanil (PC Code 128857)		

Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date September 28, 2012
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Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
LIST OF COMPANIES SENT OFFER TO PAY FOR USE OF CITE-ALL METHOD OF DATA SUPPORT					
		CITE-ALL	SYNGENTA CROP PROTECTION, INC. / 000100	PAY	
		CITE-ALL	BAYER CROPSCIENCE LP / 000264	PAY	
		CITE-ALL	VOLUNTARY PURCHASING GROUPS, INC / 007401	PAY	
		CITE-ALL	CHEMSICO / 009688	PAY	
		CITE-ALL	AGAN CHEM MFG, LTD	PAY	
		CITE-ALL	ALBAUGH INC / 042750	PAY	
		CITE-ALL	DOW AGROSCIENCES LLC / 062719	PAY	
		CITE-ALL	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	PAY	
		CITE-ALL	SPRAY DRIFT TASK FORCE / 066607	OWN	1
		CITE-ALL	OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, L.L.C. / 071754	OWN	1
		CITE-ALL	AGRICULTURAL REENTRY TASK FORCE / 071755	OWN	1
		CITE-ALL	FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C. / 073989	OWN	1
		CITE-ALL	RESIDENTIAL EXPOSURE JOINT VENTURE (REJV) / 074888	OWN	1
		CITE-ALL	AGRICULTURAL HANDLERS EXPOSURE TASK FORCE / 075234	OWN	1
		CITE-ALL	US TRIAZOLE TASK FORCE / 075576	PAY	

FOOTNOTES:

- 1 Nufarm Limited is a member of this task force.

Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date September 28, 2012
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Date: April 18, 2013	EPA Reg. No./File Symbol: 35935-00	Page 1 of 11
Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 830	GROUP A- PRODUCT IDENTITY, COMPOSITION & ANALYSIS				
830.1550	Product identity and composition	48951201	Nufarm Limited (035935)	Own	
830.1600	Description of materials used to produce the product	48951201	Nufarm Limited (035935)	Own	
830.1620	Description of production process	48951201	Nufarm Limited (035935)	Own	
830.1650	Description of formulation process	--	--	N/A	1
830.1670	Discussion of formation of impurities	48951201	Nufarm Limited (035935)	Own	
830.1700	Preliminary analysis	48951202	Nufarm Limited (035935)	Own	
830.1750	Certified limits	48951201	Nufarm Limited (035935)	Own	
830.1800	Enforcement analytical method	48951201	Nufarm Limited (035935)	Own	
830.1900	Submittal of samples	--	--	N/A	2
	GROUP B- PHYSICAL/CHEMICAL PROPERTIES				
830.6302	Color	48951203	Nufarm Limited (035935)	Own	
830.6303	Physical state	48951203	Nufarm Limited (035935)	Own	
830.6304	Odor	48951203	Nufarm Limited (035935)	Own	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	48951203	Nufarm Limited (035935)	Own	

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Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

830.6314	Oxidation/reduction: chemical incompatibility	48951203	Nufarm Limited (035935)	Own	
830.6315	Flammability	48951203	Nufarm Limited (035935)	Own	
830.6316	Explosibility	48951203	Nufarm Limited (035935)	Own	
830.6317	Storage stability	48951204	Nufarm Limited (035935)	Own	
830.6319	Miscibility	48951203	Nufarm Limited (035935)	Own	
830.6320	Corrosion characteristics	48951204	Nufarm Limited (035935)	Own	
830.6321	Dielectric breakdown voltage	48951203	Nufarm Limited (035935)	Own	
830.7000	pH	48951203	Nufarm Limited (035935)	Own	
830.7050	UV/Visible absorption	48951203	Nufarm Limited (035935)	Own	
830.7100	Viscosity	48951203	Nufarm Limited (035935)	Own	
830.7200	Melting point/melting range	48951203	Nufarm Limited (035935)	Own	
830.7220	Boiling point/boiling range	48951203	Nufarm Limited (035935)	Own	
830.7300	Density/relative density/bulk density	48951203	Nufarm Limited (035935)	Own	
830.7370	Dissociation constants in water	48951203	Nufarm Limited (035935)	Own	
830.7520	Particle size, fiber length, and diameter distribution	--	--	N/A	3
830.7550	Partition coefficient (n-octanol/water), shake flask method	48951203	Nufarm Limited (035935)	Own	

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Ingredient: Myclobutanil (PC Code 128857)		

830.7840	Water solubility: column elution method; shake flask method	48951203	Nufarm Limited (035935)	Own	
830.7950	Vapor pressure	48951203	Nufarm Limited (035935)	Own	

Footnotes:

- 1 OPPTS 830.1650 Description of Formulation Process data are not required since Myclobutanil Technical is a technical grade active ingredient and is produced by an integrated process. 40 CFR § 158.310 (e) (3)
- 2 OPPTS 830.1900 Submittal of samples data is not required since a sample of Myclobutanil (PAI) has been provided by the Basic manufacturer. 40 CFR § 158.310 (e) (9.11)
- 3 OPPTS 830.7520 Particle size, Fiber Length, and Diameter Distribution data is not required as Myclobutanil Technical is not water insoluble or fibrous. 40 CFR § 158.310 (e) (14)

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Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 835	FATE, TRANSPORT AND TRANSFORMATION				
835.1110 – 835.1410	GROUP A- LABORATORY TRANSPORT	CITE-ALL	–	PAY	
835.2120 – 835.2410	GROUP B- LABORATORY ABIOTIC TRANSFORMATION	CITE-ALL	–	PAY	
835.3100 – 835.3420	GROUP C- LABORATORY BIOLOGICAL TRANSFORMATION	CITE-ALL	–	PAY	
835.4100 – 835.4300	GROUP D- TRANSFORMATION IN WATER AND SOIL	CITE-ALL	–	PAY	
835.5045 – 835.4400	GROUP E- TRANSFORMATION CHEMICAL SPECIFIC	CITE-ALL	–	PAY	
835.6100 – 835.6400	GROUP F- FIELD DISSIPATION	CITE-ALL	–	PAY	
835.7100	GROUP G- GROUND WATER MONITORING	CITE-ALL	–	PAY	
835.8100	GROUP H- VOLATILITY FROM SOIL	CITE-ALL	–	PAY	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 840	SPRAY DRIFT				
840.1000 – 840.1200	SPRAY DRIFT	CITE-ALL	--	PAY	

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Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 850	ECOLOGICAL EFFECTS				
850.1010 – 850.1950	GROUP A- AQUATIC FAUNA	CITE-ALL	--	PAY	
850.2100 – 850.2500	GROUP B- TERRESTRIAL WILDLIFE	CITE-ALL	--	PAY	
850.3020 – 850.3040	GROUP C- BENEFICIAL INSECTS & INVERTEBRATES	CITE-ALL	--	PAY	
850.4000 – 850.4800	GROUP D- NONTARGET PLANTS	CITE-ALL	--	PAY	
850.5100 – 850.5400	GROUP E- TOXICITY TO MICROORGANISMS	CITE-ALL	--	PAY	
850.6200 – 850.6800	GROUP F- CHEMICAL SPECIFIC	CITE-ALL	--	PAY	

Signature

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Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 860					
860.1000 – 860.1900	RESIDUE CHEMISTRY	CITE-ALL	—	PAY	

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Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX

Date: April 18, 2013	EPA Reg. No./File Symbol: 35935-00	Page 8 of 11
Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 870	HEALTH EFFECTS				
870.1100	Acute Oral Toxicity	00141662 & 00141664	--	OLD	
870.1200	Acute Dermal Toxicity	00141663		OLD	
870.1300	Acute Inhalation Toxicity	40357101		OLD	
870.2400	Primary Eye Irritation	00141663		OLD	
870.2500	Acute Dermal Irritation	00141163		OLD	
870.2600	Skin Sensitization	40357102		OLD	
870.3050 – 870.3800	GROUP B- SUBCHRONIC TOXICITY	CITE-ALL	--	PAY	
870.4100 – 870.4300	GROUP C- CHRONIC TOXICITY	CITE-ALL	--	PAY	
870.5100 – 870.5915	GROUP D- GENETIC TOXICITY	CITE-ALL	--	PAY	
870.6100 – 870.6855	GROUP E- NEUROTOXICITY	CITE-ALL	--	PAY	
870.7200 – 870.7800	GROUP F- SPECIAL STUDIES	CITE-ALL	--	PAY	
870.8223 – 870.8800	GROUP G- CHEMICAL SPECIFIC	CITE-ALL	--	PAY	

Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date April 18, 2013
---	--	-------------------------------

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: April 18, 2013

EPA Reg. No./File Symbol: 35935-00

Page 9 of 11

Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 875	OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.1100 – 875.1600	GROUP A- APPLICATOR EXPOSURE MONITORING	CITE-ALL	–	PAY	
875.2100 – 875.2900	GROUP B- POSTAPPLICATION EXPOSURE MONITORING	CITE-ALL	--	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

April 18, 2013



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: April 18, 2013

EPA Reg. No./File Symbol: 35935-00

Page 10 of 11

Nufarm Limited
C/O Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Product: Myclobutanil Technical

Ingredient: Myclobutanil (PC Code 128857)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS SERIES 890	ENDOCRINE DISRUPTOR SCREENING				
890.1100 – 890.1600	EDSP TIER 1	CITE-ALL	--	PAY	

Signature

Name and Title

Nathan P. Ehresman / Director, Regulatory Affairs

Date

April 18, 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: April 18, 2013	EPA Reg. No./File Symbol: 35935-00	Page 11 of 11
Nufarm Limited C/O Nufarm Americas Inc. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product: Myclobutanil Technical	
Ingredient: Myclobutanil (PC Code 128857)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
LIST OF COMPANIES SENT OFFER TO PAY FOR USE OF CITE-ALL METHOD OF DATA SUPPORT					
		CITE-ALL	SYNGENTA CROP PROTECTION, INC. / 000100	PAY	
		CITE-ALL	BAYER CROPSCIENCE LP / 000264	PAY	
		CITE-ALL	VOLUNTARY PURCHASING GROUPS, INC / 007401	PAY	
		CITE-ALL	CHEMSICO / 009688	PAY	
		CITE-ALL	AGAN CHEM MFG, LTD	PAY	
		CITE-ALL	ALBAUGH INC / 042750	PAY	
		CITE-ALL	DOW AGROSCIENCES LLC / 062719	PAY	
		CITE-ALL	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	PAY	
		CITE-ALL	SPRAY DRIFT TASK FORCE / 066607	OWN	1
		CITE-ALL	OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, L.L.C. / 071754	OWN	1
		CITE-ALL	AGRICULTURAL REENTRY TASK FORCE / 071755	OWN	1
		CITE-ALL	FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C. / 073989	OWN	1
		CITE-ALL	RESIDENTIAL EXPOSURE JOINT VENTURE (REJV) / 074888	OWN	1
		CITE-ALL	AGRICULTURAL HANDLERS EXPOSURE TASK FORCE / 075234	OWN	1
		CITE-ALL	US TRIAZOLE TASK FORCE / 075576	PAY	

FOOTNOTES:

- 1 Nufarm Limited is a member of this task force.

Signature 	Name and Title Nathan P. Ehresman / Director, Regulatory Affairs	Date April 18, 2013
----------------------	--	-------------------------------

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition					X	
830.1600	Description of materials used to produce the product					X	
830.1650	Description of formulation process					X	
830.1670	Discussion on the formation of impurities					X	
830.1700	Preliminary analysis					X	
830.1750	Certified limits (158.345)					X	
830.1800	Enforcement analytical method					X	

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color					X	
830.6303	Physical State					X	
830.6304	Odor					X	
830.6313	Stability to normal and elevated temperatures metal and metal ions					NR	
830.6314	Oxidation/Reduction (Chemical incompatibility)					X	
830.6315	Flammability					NR	
830.6316	Explosibility					NR	
830.6317	Storage stability					X	in progress
830.6319	Miscibility					NR	
830.6320	Corrosion Characteristics					X	in progress
830.6321	Dielectric Breakdown Voltage					NR	
830.7000	pH					X	
830.7050	UV/ Visible Absorption					X	
830.7100	Viscosity					NR	
830.7200	Melting Point					X	
830.7220	Boiling Point					X	
830.7300	Density					X	
830.7370	Dissociation Constant					NA	
830.7550	Partition Coefficient					X	
830.7840	Water Solubility					X	
830.7950	Vapor Pressure					X	

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)			X	
870.1200	Acute Dermal (LD50)			X	
870.1300	Acute Inhalation (LC50)			X	
870.2400	Acute Eye Irritation			X	
870.2500	Acute Dermal Irritation			X	
870.2600	Dermal Sensitization			X	

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					

Receipt for Section 3



S: 925407

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 35935 NUFARM LIMITED



Risk Manager: Registration Division, Risk Management Team 20

Product #: 35935-00 Product Name: MYCLOBUTANIL TECHNICAL

Override#:

Me Too Section3: 62719-407 Me Too Product Name: RH-3866 TECHNICAL

Application Date: 28-Sep-2012

OPP Rec'd Date: 11-Oct-2012

Front End Date: 12-Oct-2012

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

Fast Track ☐

New Ingredient: ☐

Receipt Description:

Associated with e-Submission package 3503. Application for registration

New Ingredient Request Date:

New Ingredient Received Date:

Form A ☐ Signature Date:

Form B ☐ Signature Date:

View/Edit

E-SUBMISSION

21-Day Screen Completed by
Contractor

21-Day Expires on 11/1/12

Jacket # 35935-00

MRID# 489512

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Stephen Schauble

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 10/11/12

Experts In-Processing Signature: MP

Date 10/18/12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>35935-00</u>		EPA Receipt Date: <u>10/11/12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <div style="text-align: center; margin-top: 5px;">No inerts</div>			yes	no	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			yes	no	
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 17, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-470782
EPA File Symbol or Registration Number: 35935-OO
Product Name: MYCLOBUTANIL TECHNICAL
EPA Receipt Date: 11-Oct-2012
EPA Company Number: 35935
Company Name: NUFARM LIMITED

NATHAN P. EHRESMAN
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 101
MORRISVILLE, NC 27560-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310
NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED
SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO
OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER
REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD
ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);CHILD
RESISTANT PACKAGING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "m she".

Front End Processing Staff
Information Technology & Resources Management Division

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * Technical and impurities only, no inerts to review.
- * Studies passed PRN 11-03 review.
- * Application form had the wrong product name. The registrant was contacted to rectify this issue and a revised application form was sent.
- * Jacket passed.

AB

MRID: 489512

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Nathan P. Ehrsman

Phone #: 919-379-2515

Email: nathan.ehrsman@us.nufarm.com

First Call/Initials: MB

Date: 10/19/12

Time: 9:46 AM

Second Call/Initials:

Date:

Time:

This is Aswathy Balan, EPA contractor.

I'm calling regarding your submission in support of

Rep # 35935-00.

Passed

We have found the following deficiencies regarding:

PR Notice 2011-3: Yes or No

Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

* Application form has wrong product name.

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: Aswathy Balan.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



Re: Submission to EPA: product Myclobutanil technical (Reg# 35935-OO)

nathan.ehresman

to:

Aswathy Balan

10/22/2012 08:50 AM

Cc:

Sree Nair

Hide Details

From: nathan.ehresman@us.nufarm.com

To: Aswathy Balan/DC/USEPA/US@EPA

Cc: Sree Nair/DC/USEPA/US@EPA

1 Attachment



035935-000XX.20120928.8570-1 Application Form.pdf

Brian- here you go.

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919.379.2515
Mobile: 919.930.4198
nathan.ehresman@us.nufarm.com

From: Balan.Aswathy@epamail.epa.gov
To: nathan.ehresman@us.nufarm.com,
Cc: Nair.Sree@epamail.epa.gov

Date: 10/19/2012 09:46 AM

Subject: Submission to EPA: product Myclobutanil technical (Reg# 35935-00)

Dear Mr. Ehresman,

This email is to address one issue found regarding your Application for registration of the product Myclobutanil technical (Reg# 35935-00). The Application form (8570-1) is having the wrong product name under Box 4. Please verify and send the revised form either by email (in pdf) or to our secure fax line 703-305-5060. Please contact me if you have any questions.

Thanks,

Aswathy Balan

EPA Contractor

2777 S. Crystal Drive, S4811

Arlington, VA 22202

Ph: 703-347-8787

Fax: 703-305-5060

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Nufarm Americas Inc. and its affiliated companies.

Fax: +1 630 455 2001.

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Reg #	Date Submitted to EPA	Electronic file name
035935-__	September 28, 2012	035935-000XX.20120928.Draft_label

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature

09-28-2012

Date

Nathan P. Ehresman

Name (typed)

Director, Regulatory Affairs

Title

E-SUBMISSION



Pay.gov Payment Confirmation : PRIA Service Fees
paygovadmin to: nathan.ehresman@us.nufarm.com

09/27/2012 10:22 AM

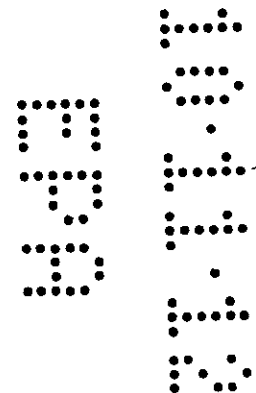
Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2584C2H8
Agency Tracking ID: 74361211434
Transaction Type: Sale
Transaction Date: Sep 27, 2012 10:20:32 AM

Account Holder Name: Nathan Ehresman
Transaction Amount: \$4,807.00
Billing Address: 4020 Aerial Center Parkway
Billing Address 2: Suite 101
City: Morrisville
State/Province: NC
Zip/Postal Code: 27560
Country: USA
Card Type: AmericanExpress
Card Number: *****2004

Decision Number:
Registration Number:
Company Name: Nufarm Ltd
Company Number: 35935
Action Code: R310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



E-SUBMISSION

Confidential Statement of Formula may be entitled to confidential treatment